§ 106-135. Regulations for sale of new drugs.

(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless:

(1) An application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act, or

(2) When not subject to the federal act, by virtue of not being a drug in interstate commerce, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner an application setting forth

a. Full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

b. A full list of the articles used as components of such drug;

c. A full statement of the composition of such drug;

d. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

e. Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

f. Specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subdivision (a)(2) of this section shall become effective on the one hundred eightieth day after the filing thereof, except that if the Commissioner finds, after due notice to the applicant and giving him an opportunity for hearing,

(1) That the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or

(2) The methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug is inadequate to preserve its identity, strength, quality, and purity; or

(3) Based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the Commissioner.

(d) The Commissioner shall promulgate regulations for exempting from the operation of the foregoing subsections and subdivisions of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Commissioner among other conditions relating to the protection of the public health, provide for conditioning such exemption upon

(1) The submission to the Commissioner, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed

agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) The establishment and maintenance of such records, and the making of such reports to the Commissioner, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Commissioner finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible, or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Commissioner reports on the investigational use of drugs; provided, that regulations adopted under section 505(i) of the federal act may be adopted by the Commissioner as the regulations in this State.

(e) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Commissioner, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Commissioner may by general regulation, or by order with respect to such application, prescribe: Provided, however, that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Commissioner deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Commissioner.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Commissioner, permit such officer or employee at all reasonable times to have access to and copy and certify such records.

(f) The Commissioner may, after affording an opportunity for public hearing, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health.

(g) This section shall not apply:

(1) To a drug sold in this State or introduced into interstate commerce at any time prior to the enactment of the federal act, if its labeling contained the same representations concerning the conditions of its use; or

(2) To any drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum-Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.); or

(3) To any drug which is subject to G.S. 106-134 (14) of this Article. (1939, c. 320, s. 16; 1975, c. 614, s. 31.)